*Sixty-Sixth Meeting of the*

# Obstetrics and Gynecology Devices Panel

*Monday & Tuesday, July 22 & 23, 2002*
*DoubleTree Hotel, Rockville, Maryland*

## Conceptus Essure® Micro-Insert System (P020014)

DRAFT Agenda, Monday, July 22, 2002

8:30-9:00 Introductory remarks
- *Colin Pollard, Chief, Obstetrics and Gynecology Devices Branch*

9:00-9:30 Medical Device Postmarket Surveillance: Vacuum Assisted Delivery Devices
- *Danica Marinac-Dabic, M.D., M.M.Sc., Office of Surveillance and Biometrics*
- *Barry S. Schifrin, M.D., Glendale Adventist Medical Center, Glendale, California*

9:30-10:00 Open public hearing

*Conceptus Essure Micro-Insert System (P020014)*

10:00-11:00 Presentation by Sponsor
- *Cindy Domecus, Senior Vice President, Clinical Research and Regulatory Affairs*
- *Jay Cooper, M.D., Women's Health Research, University of Arizona*
- *Thomas Wright, M.D., Columbia University*
- *Charles S. Carignan, M.D., Vice President, Clinical Research and Medical Affairs*

11:00-11:15 Break

11:15-12:15 Presentation by FDA
- *Lisa D. Lawrence, R.N., Lead Reviewer*
- *Julia A. Corrado, M.D., Medical Officer*
- *Gene A. Pennello, Ph.D., Statistician*

12:15-1:15 Lunch

1:15-3:15 Panel discussion

3:15-3:30 Break

3:30-4:00 Open public hearing

4:00-5:00 Panel deliberations and vote

| | |
|---|---|
| 5:00 | Adjourn |

** all times are approximate*

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## DRAFT Roster

Jorge D. Blanco, M.D. (Chair)
Regional Perinatal Center
Odessa Regional Hospital
Odessa, TX

Carol L. Brown, M.D.
Weill-Cornell Medical College
Memorial Sloan-Kettering Cancer Center
New York, NY

Anil K. Dubey, Ph.D., H.C.
Department of Obstetrics & Gynecology
George Washington University Medical Center
Washington, D.C.

Kinley Larntz, Ph.D.
Scottsdale, AZ

Kleia R. Luckner, J.D., M.S.N.
(Consumer Representative)
Women's Ambulatory Health
The Toledo Hospital
Toledo, OH

Mary Lou Mooney, R.A.C.
(Industry Representative)
SenoRx., Inc.
Aliso Viejo, CA

Kenneth L. Noller, M.D.
Department of Obstetrics & Gynecology
Tufts University Medical School
Boston, MA

Mary Jo O'Sullivan, M.D.
Department of Obstetrics & Gynecology
University of Miami/Jackson Memorial Hospital, Hoetz Center
Miami, FL

Subir Roy, M.D.
Department of Obstetrics & Gynecology
USC School of Medicine
Los Angeles, CA

David B. Seifer, M.D.
Division of Reproductive Endocrinology & Infertility
University of Medicine & Dentistry of New Jersey
New Brunswick, NJ

Nancy C. Sharts-Hopko, Ph.D.
College of Nursing
Villanova University
Villanova, PA

Gerald J. Shirk, M.D.
Ob/Gyn Associates
Cedar Rapids, IA

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## Conceptus Essure® Micro-Insert System (P020014)

## DRAFT Discussion Questions

Effectiveness

1. The results for the single-arm clinical trials featuring bilateral placement of the gamma version of the Essure Micro-insert are provided below. How does the effectiveness of the Essure Micro-insert compare to other available methods for female tubal sterilization?

| | number patients | number pregnancies | estimated pregnancy rate, 95% confidence interval |
|---|---|---|---|
| Pivotal Trial | | | |
| 1 year | 408 | 0* | 0 - 0.74% |
| Phase II Trial | | | |
| 1 year | 194 | 0 | 0 - 1.55% |
| 2 year** | 149 | 0 | 0 - 2.01% |

** 4 luteal phase pregnancies*
*** 1 pregnancy in patients with earlier ("beta") version of device*

2. The PMA presents results from a pre-hysterectomy 'proof of concept' study (n=52) where fallopian tube specimens were examined histologically following device placement.
   a. What do the results of this study indicate about the mechanism of action of the Essure device?
   b. Can results from this study shed any light on the likelihood of tubal recanalization in a long-term setting?

3. In the three months following device placement, the patient is suppose to stay on alternate contraception to allow for sufficient tissue in-growth to produce tubal occlusion.

   In the Pivotal Study, an HSG confirming correct device placement and tubal occlusion was needed before the patient stopped alternate contraception. The Pivotal Study showed that the rate of bilateral occlusion was 96% of the number of correctly placed devices.

   The Sponsor is proposing that in commercial use, alternate contraception can be stopped 3 months post-placement if a *pelvic x-ray* (i.e. not an HSG) indicates satisfactory position of the device. Is the Sponsor's proposal adequate?

4. Do the results of these studies enable us to make any prediction about the long term efficacy of this device?

5. There was a 12% failure rate of bilateral placement on the first attempt. In comparison to failure of laparoscopic sterilization at first attempt, is this failure rate acceptable?

Safety

6. Is the safety profile of this device acceptable?

Labeling & Training

7. Are the professional labeling (Volume 1, Exhibits 1, 2, 3 of the Panel package) and the training materials (Volume 1, Exhibits A, B, C of the Panel package) provided by the Sponsor sufficient to ensure appropriate use of the Essure Micro-insert system?

Post-approval Studies

8. The Sponsor has proposed to follow study subjects from the pivotal study for a total of five years. Is this post-approval study plan necessary and sufficient?